

Food and Drug Administration  
Washington DC 20204

David Kropp  
Manager Quality Assurance  
and Regulatory Affairs  
Pharmavite Corporation  
P.O. Box 9606  
15451 San Fernando Mission Boulevard  
Mission Hills, California 91346-9606

Re: Nutritional Support Statement Notification

Dear Mr. Kropp:

This acknowledges receipt on July 19, 1995, of your letter, dated July 18, 1995, notifying the Food and Drug Administration (FDA) that the dietary supplement product, Great Breath, is being marketed with a statement of nutritional support on its label or in its labeling.

Pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act), a manufacturer must notify FDA no later than 30 days after the first marketing of a dietary supplement product that bears a nutritional support statement on its label or in its labeling. Pursuant to the act, a manufacturer of such a product must have substantiation that the nutritional support statement is truthful and not misleading. In addition, the nutritional support statement must include, prominently displayed and in bold face type, the following: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

No action on the part of FDA is required before a manufacturer can market a dietary supplement product bearing a nutritional support statement on its label or in its labeling. While the act requires that certain information appear on the label of a dietary supplement in conjunction with such statements, FDA does not approve them. This letter serves only to acknowledge the receipt by FDA of your notification.

Sincerely yours,

Margaret C. Binzer  
Consumer Safety Officer  
Regulatory Branch  
Division of Programs  
and Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety  
and Applied Nutrition

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